April 8, 2004

INFORMATION DISCLOSURE STATEMENT Patent Application Docket No. GJE-44D1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants

Robert Graham Feldman, Gordon Dougan, Joseph David Santangelo, David

William Holden, Jacqueline Elizabeth Shea, Zoe Hindle

Docket No.

GJE-44D1

For

Attenuated Microorganisms for the Treatment of Infection

Mail Stop PATENT APPLICATION Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§1.97 AND 1.98

Sir:

In accordance with 37 CFR §§1.97 and 1.98, Applicants would like to bring to the attention of the Examiner, the references cited in the following patent application:

U.S. Serial No. 09/569,601, filed May 9, 2000.

The subject application claims the benefit under 35 USC §120 of the filing date of patent application Serial No. 09/569,601. Applicants respectfully request that the copies of references supplied in the Information Disclosure Statement of the 09/569,601 application, as well as any references cited during the prosecution thereof, be made of record in the subject application. As copies of the references made of record in the 09/569,601 application, and cited on the attached form PTO/SB/08, can be found in the 09/569,601 casefile, copies of those references are not provided herewith.

It is respectfully requested that the references cited on the attached form PTO/SB/08 be considered in the examination of the subject application and that their consideration be made of record.

Applicants respectfully assert that the substantive provisions of 37 CFR $\S\S1.97$ and 1.98 are met by the foregoing statements.

Respectfully submitted,

Doran R. Pace

Patent Attorney

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DRP/mdp

Attachment: Form PTO/SB/08

PTO/SB/08A (08-03)

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Substitute for form	1449A/PTO			Complete if Known		
INFORMA	TION DIC	CI OCUDI	_	Application Number		
INFORMA			_	Filing Date	April 8, 2004	
(use as many sheets as necessary)				First Named Inventor	Robert Graham Feldman	
				Art Unit		
				Examiner Name		
Sheet	1	of	3	Attorney Docket Number	GJE-44D1	

U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
	U1	US-5,876,931	03-02-1999	Holden	All		
	U2	US-5,643,579	07-01-1997	Hung et al.	All		
	U3	US-					
	U4	US-					
	U5	US-					
	U6	US-					
	U7	US-					
	U8	US-					
	U9	US-			·		

FOREIGN PATENT DOCUMENTS							
		Foreign Patent Document			Barra Cal	Т	
Examiner Initials*	Cite No. 1	Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T	
	F1	EPO 0889120 B1	01-07-1999	Microscience Limited	All		
	F2	WO 00/14240	03-16-2000	CREATOGEN BIOSCIENCES GMBH	All		
	F3						
	F4					!	
	F5					\vdash	
	F6					T	
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Examiner	Date	
Signature	Considered	

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Complete if Known Substitute for form 1449B/PTO Application Number INFORMATION DISCLOSURE **Filing Date** April 8, 2004 STATEMENT BY APPLICANT **First Named Inventor** Robert Graham Feldman **Group Art Unit** (use as many sheets as necessary) **Examiner Name** Sheet 2 3 **Attorney Docket Number** GJE-44D1

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	R1	MEDINA, E. et al. "Pathogenicity Island 2 Mutants of Salmonella typhimurium Are Efficient Carriers for Heterologous Antigens and Enable Modulation of Immune Responses", Infection and Immunity, 1999, pp. 1093-1099, Vol. 67, No. 3.	
	R2	VALENTINE, P.J. et al. "Identification of Three Highly Attenuated Salmonella typhimurium Mutants That Are More Immunogenic and Protective in Mice than a Prototypical aroA Mutant", Infection and Immunity, 1998, pp. 3378-3383, Vol. 66, No. 7.	
	R3	HENSEL, M. et al. "Genes Encoding Putative Effector Proteins of the Type III Secretion System of Salmonella Pathogenicity Island 2 are Required for Bacterial Virulence and Proliferation in Macrophages", Molecular Microbiology, 1998, pp. 163-174, Vol. 30, No. 1.	
	R4	HENSEL, M. et al. "Analysis of the Boundaries of Salmonella Pathogenicity Island 2 and the Corresponding Chromosomal Region of Escherichia coli K-12", Journal of Bacteriology, 1997, pp. 1105-1111, Vol. 179, No. 4.	
	R5	HENSEL, M. et al. "Functional Analysis of ssaJ and ssaK/U Operon, 13 Genes Encoding Components of the Type III Secretion Apparatus of Salmonella Pathogenicity Island 2", Molecular Microbiology, 1997, pp. 155-167, Vol. 24, No. 1.	
	R6	SHEA, J.E. et al. "Influence of the Salmonella typhimurium Pathogenicity Island 2 Type III Secretion System on Bacterial Growth in the Mouse", Infection and Immunity, 1999, pp. 213-219, Vol. 67, No. 1.	
	R7	SHEA, J.E. et al. "Identification of a Virulence Locus Encoding a Second Type III Secretion System in Salmonella typhimurium", Proc. Natl. Acad. Sci. USA, 1996, pp. 2593-2597, Vol. 93.	
	R8	CHATFIELD, S. N. et al. "Construction of a Genetically Defined Salmonella typhi Ty2 aroA, aroC Mutant for the Engineering of a Candidate Oral Typhoid-Tetanus Vaccine", Vaccine, 1992, pp. 53-60, Vol. 10, No. 1.	
	R9	LEVINE, M.M. et al. "Attenuated Salmonella as Live Oral Vaccines Against Typhoid Fever and as Live Vectors", Journal of Biotechnology, 1996, pp. 193-196, Vol. 44, No. 1-3.	
	R10	DOUGAN, G. et al. "Live Bacterial Vaccines and Their Application as Carriers for Foreign Antigens", Advances in Veterinary Science and Comparative Medicine, 1989, pp. 277-300, Vol. 33.	
	R11	HOHMANN, E.L. et al. "Evaluation of a phoPlphoQ-deleted, aroA-deleted Live Oral Salmonella typhi Vaccine Strain in Human Volunteers", Vaccine, 1996, pp. 19-24, Vol. 14, No. 1.	
	R12	LOWE, D.C. et al. "Characterization of Candidate Live Oral Salmonella typhi Vaccine Strains Harboring Defined Mutations in aroA, aroC, and htrA", Infection and Immunity, 1999, pp. 700-707, Vol. 67, No. 2.	Γ
 	R13	SCHODEL, F. et al. "Hepatitis B Virus Nucleocapsid/pre-S2 Fusion Proteins Expressed in Attenuated Salmonella for Oral Vaccination", Journal of Immunology, 1990, pp. 4317-4321, Vol. 145, No. 12.	

Examiner Date Signature Considered

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				LOSURE	Application Number		
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(use as many sheets as necessary)					Group Art Unit		
					Examiner Name		
Sh	neet	3	of	3	Attorney Docket Number	GJE-44D1	

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²			
	R14	PLOTKIN, S. A. <u>Vaccines</u> , 1988, p. 571, W.B Saunders Co., Philadelphia.				
	R15					
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